MAY 1 9 2000

13.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter and Contact Person: Mary M. Wilen
Rochester Medical Corporation

Name of the Device:
Classification Name: Urological Catheter
Proprietary Name: Rochester Medical Corporation Hydrophilic Foley Catheter
Personal® Catheter (Standard or Hydrophilic coated)

Predicate Devices:
Rochester Medical All Silicone Foley Catheter K981612
Bardex Hydrogel Coated Foley Catheter K910197
Bardex LubriSil Foley Catheter K984084 & K984136
Rochester Medical Personal® Catheter K970704
Astra Tech LoFric Urinary Catheter K896750

Intended Use of the Device
For urological use only. Rochester Medical Corporation Hydrophilic Silicone Two and Three-Way Foley Catheters and Personal® Catheter (Standard or Hydrophilic coated) are intended for use for bladder management including urine drainage, collection and measurement. The devices are generally passed to the urinary bladder via the urethra but in some cases may be placed suprapubically.

In some cases the Foley catheters, especially those with larger balloons, are used to reduce bleeding after urological procedures such as prostatectomy. Three-Way Foley catheter provide a second lumen that is used for bladder installation or irrigation with fluids.

Device Description
Two and Three Way Hydrophilic Silicone Foley - The catheters consists of standard Two and Three-Way Foley Catheters with a hydrophilic outer coating on the catheter tube. The catheters are available in lengths range 10.6 to 15.8, French sizes from 6 to 26 and balloon sizes 1.5cc to 30cc.

Personal Catheter - The catheter is available in four configurations including a non-hydrophilic

One Rochester Medical Drive Stewartville, MN 55976 ISO 9001 CERTIFIED Tel: (507) 533-9600 Fax: (507) 533-9726

and a hydrophilic coated single lumen catheter with either two or four drainage eyes on the proximal tip. It is available in a variety of sizes including pediatric, male and female lengths in French sizes 6 to 18.

Technological Characteristics

The catheters described in the 510(k) have similar technological and performance characteristics to the predicate devices. The catheters are manufactured from silicone elastomer and have a hydrophilic outer coating. The predicate devices are manufactured from similar materials such as silicone elastomers and latex and some have a lubricious coating. The catheters are supplied in French sizes ranging from 6 to 26 and balloon capacities 1.5cc to 30cc. The predicate devices are available in French sizes from 6 to 26 and balloon capacities 1.5cc to 75cc. The device is supplied in pediatric, male and female lengths. The predicate devices are supplied in various lengths. All of the devices are supplied sterile for single use.

Testing and Results

Rochester Medical Corporation Hydrophilic Silicone Foley and Hydrophilic Personal Catheter have been tested to and meet the following test requirements.

Rochester Medical Dimensional Specifications
Rochester Medical Lubricity Test
Rochester Medical Hydrophilic Coating Durability Test
ASTM 623 F 98 Standard Performance Specification for Foley Catheter:
Clause 5.1 "Flow Rate Through the Drainage Lumen"
Clause 5.2 "Balloon Integrity, Resistance to Rupture" (Foley only)
Clause 5.3 "Inflated Balloon Response to Pullout" (Foley only)*
Clause 5.4 "Balloon Volume Maintenance" (Foley only)
Clause 5.5 "Balloon Size and Shaft Size" (Foley only)**
Clause 5.6 "Deflation Reliability" (Foley only)

* The 26 French catheter could not be tested because it would not fit through the 28 French orifice of the text fixture.(See below for information on catheter tip diameters.) All other catheters tested met this requirement.

** Due to the proprietary manufacturing process that allows Rochester Medical to manufacture catheters with balloons that are incorporated into the catheter wall rather than being applied during a secondary operation, the tip diameter is equivalent to the balloon diameter. All balloon diameters comply with the standard.

Biocompatibility Testing:
Cytotoxicity, ISO Elution L-929 Cells, 48 hour MEM extract
ISO Sensitization in the Guinea Pig - Maximization Method (Saline and CSO extracts)
ISO Acute Intracutaneous Reactivity Test (Saline and CSO extracts)
ISO Acute Systemic Toxicity ((Saline and CSO extracts)
Urinary Bladder Irritation Study with Histopathology
ISO Muscle Implantation Study with Histopathology

Aged Product Testing:
Testing of products aged under ambient and accelerated conditions indicate that there are no adverse effects on device materials or performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Ms. Mary M. Wilen
Director of Clinical and Regulatory Affairs
Rochester® Medical
One Rochester Medical Drive
Stewartville, MN 55976

Re: K000723
Hydrophilic Silicone Foley Catheter and
Personal® Catheter
Dated: March 3, 2000
Received: March 6, 2000
Regulatory Class: II
21 CFR §876.5130/Procode: 78 KOD

Dear Ms. Wilen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) NUMBER (if Known): K000723

DEVICE NAME: Hydrophilic Silicone Foley Catheter
Personal® Catheter (hydrophilic and non-hydrophilic)

INDICATIONS FOR USE:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Segerson

)ivision Sign-Off)
/ivision of Reproductive, Abdominal, ENT,
nd Radiological Devices
10(k) Number K000723

Prescription Use ✓ OR Over-The-Counter-Use _____
(Per 21 CFR 801.109)